

Applicants : Yingru Wu, et al.
Serial No. : 10/594,785
Filed : September 17, 2007
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October 1, 2010 Office Action

REMARKS

Claims 117-142 were pending in the subject application. By this Amendment, applicants have hereinabove amended claims 117, 118, 120, 122, 124, 126-128, 131, 135, 137, 138, and 140-142. Applicants maintain that the amendments to the claims raise no issue of new matter. Accordingly, applicants respectfully request entry of this Amendment.

Restriction Requirement Under PCT Rule 13.2

The October 1, 2010 Office Action withdrew claims 118, 121-122, 124-126, 128, 130, 132, 134, 138, and 140-142 from consideration and objected to claims 119 and 123 for being drawn to non-elected inventions. On page 3 of the October 1, 2010 Office Action, the Examiner alleged that the special technical feature of applicant's invention is **a method** of altering fibre initiation and/or elongation comprising genetically manipulating a plant such that the production of a polypeptide is increased, wherein the amino acid sequence of the polypeptide is at least 95% identical to the amino acid sequence of the polypeptide encoded by Seq ID No. 38.

The Examiner alleged that the special technical feature is not shared or linked to a method of altering fibre initiation and/or elongation comprising decreasing expression of production of said polypeptide (Group II), a method of assessing the potential of a fibre producing plant (Group III), an isolated polypeptide of Group IV, a polynucleotide which is a catalytic polynucleotide (Group VI), a method of breeding a fibre producing plant (Group VII), or a method of

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identifying an agent which alters fibre initiation and/or elongation (Group VIII). Thus, the Examiner stated that the withdrawn claims lack the same or corresponding special technical feature which is a contribution over the prior art shared with Group I, which was elected with traverse in applicant's July 1, 2010 response to the December 28, 2009 Office Action.

Applicants' Reply

In response, Applicant's respectfully disagree. The special technical feature is a **polypeptide** comprising consecutive amino acids whose sequence is identical to the amino acid sequence of the polypeptide encoded by the nucleotide sequence set forth in SEQ ID NO: 38. This feature is an element of every pending claim.

The **polypeptide** recited in the pending claims (not the method as asserted by the examiner) is the special technical feature because it represents a "contribution" over the prior art as evidenced by the October 1, 2010 Office Action. Chapter 10 paragraph 4 of the PCT International Search and Preliminary Examination Guidelines (attached hereto as **Exhibit 1**) clearly states that under Rule 13.2, if "there is a single general inventive concept that appears novel and involves inventive step, then objection of lack of unity does not arise." Claims 117-142 satisfy the requirement of unity of invention and recite a contribution over the prior art because "a polypeptide comprising consecutive amino acids whose sequence is identical to the amino acid sequence encoded by the nucleotide sequence set forth in SEQ ID NO: 38" and "a polypeptide comprising consecutive amino acids whose sequence

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is identical to the amino acids sequence set forth in SEQ ID NO: 12" are **novel and inventive over the prior art** as evidenced by the October 1, 2010 Office Action.

Neither the purified nucleotide sequence SEQ ID NO: 38, nor the isolated amino acid sequence SEQ ID NO: 12 encoded by it, is disclosed in the prior art. Since the technical feature linking claims 117-142 has not been taught in the prior art it is novel, and applicants maintain that they are entitled to prosecution of claims relying on the feature in the same application pursuant to PCT Rule 13.2.

Accordingly, applicants respectfully request the examination of claims 117-142 of the subject application.

Rejection under 35 U.S.C. §112, 2nd paragraph

On page 4 of the October 1, 2010 Office Action, the Examiner rejected claims 127, 129, 131, 133, 135, 137 and 139 under 35 U.S.C. §112, second paragraph. The Examiner alleged that the term "high stringency conditions" in claim 127 was a relative term which rendered the claim indefinite. The Examiner also alleged that the term "high stringency conditions" was not defined by the claim, that the specification did not provide a standard for ascertaining the requisite degree of stringency, and that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Examiner further alleged that the limitation "The transgenic seed" recited in claim 137 lacked sufficient antecedent basis.

Applicants' Reply

In response, without conceding the correctness of the

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Examiner's position but solely to expedite prosecution, applicants have hereinabove amended claim 127 to recite, "An isolated and/or exogenous polynucleotide comprising a polynucleotide selected from the group consisting of: i) a polynucleotide comprising consecutive nucleotides whose nucleotide sequence is set forth in SEQ ID NO: 38; and ii) a polynucleotide which encodes a polypeptide comprising consecutive amino acids whose sequence is identical to the amino acid sequence encoded by the nucleotide sequence set forth in SEQ ID NO: 38" (emphasis added). Applicants respectfully submit that claim 127 as amended is definite.

Applicants have also similarly amended the other claims subject to this rejection.

Accordingly, the rejection of claims 127, 129, 131, 133, 135, 137, and 139 under 35 U.S.C. §112, second paragraph, is now moot.

Rejection under 35 U.S.C. §112, 1st paragraph-written description

On page 5 of the October 1, 2010 Office Action, the Examiner rejected claims 117, 120, 123, 127, 129, 131, 133, 135, 137 and 139 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleged that there was not enough support in the specification for the recitation, "exhibiting at least 95% identity" to the protein encoded by SEQ ID No. 38 because essential regions of the protein encoded by SEQ ID No. 38 were not identified. The Examiner further alleged that features common to members of the claimed genus of polynucleotides were not described. Therefore, the Examiner alleged that the specification failed to provide an

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adequate written description to support the breath of the claims.

Applicants' Reply

In response, without conceding the correctness of the Examiner's position but solely to expedite prosecution, applicants have hereinabove amended the claims to not recite the "95% identity" language alleged to not have written description. SEQ ID NO: 38 and SEQ ID NO:12 are clearly described in the specification of subject application.

Accordingly, the rejection of claims 117, 120, 123, 127, 129, 131, 133, 135, 137 and 139 under 35 U.S.C. §112, first paragraph-written description, is moot.

Rejection under 35 U.S.C. §112, 1st paragraph-enablement

On page 7 of the October 1, 2010 Office Action, the Examiner rejected claims 117, 119-120, 123, 127, 129, 131, 133, 135-137 and 139 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner alleged that the applicants have not reduced their invention to practice by increasing expression of any of the claimed sequences in a plant or produced a plant exhibiting altered fibre initiation and/or elongation. Additionally, the Examiner alleged the recitation of "high stringency conditions" in claim 127 and the breath claimed by the recitation "at least 95% identical" (each discussed herein above) placed a burden of undue experimentation on one of ordinary skill in the art in the screening through a multitude of non-exemplified sequences (page 10).

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Applicants' Reply

In response, without conceding the correctness of the Examiner's position but solely to expedite prosecution, applicants have amended the claims herein to no longer recite "95% identical". As amended, the claims herein are enabled by the specification.

In Example 5, the subject specification identifies "Fibre Initiation Genes" that have reduced expression in cotton mutants with reduced fibre production compared to wild-type plants. One of the identified genes is *GhMYB25*, and another is *GhMYB25-like*. *GhMYB25* and *GhMYB25-like* share a high degree of cDNA and amino acid sequence conservation (subject application, Example 5), both have similar gene expression profiles (subject application, Examples 5, 6, and 14), and both have reduced expression in a cotton mutant with reduced fibre production (Table 4).

Consequently, in Example 12 of the subject application, the function of the *GhMYB25* gene is analyzed and also represents the expected function of the *GhMYB25-like* gene. Example 13 describes how transgenic fibre producing plants with enhanced or reduced expression of *GhMYB25* or *GhMYB25-like* may be generated.

Increased Plant Fibre Initiation and/or Elongation Upon
Increased *GhMYB25-like* Expression

Example 12 of the subject application reports on the effects of increased expression of *GhMYB25* in transgenic tobacco plants. The effects of increased *GhMYB25* expression on trichome formation in tobacco plants provide a model of the

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effects of such gene on fibre initiation or elongation in fibre producing plants. Increased trichome production on the leaves of transgenic tobacco plants over-expressing the *GhMYB25* transgene is predictive of increased fibre initiation and/or elongation in transgenic fibre producing plants upon over-expression of that transgene. See, e.g. paragraphs 4-10 of January ___, 2011 Declaration of Danny Llewellyn, **Exhibit 2** (hereinafter "Danny Llewellyn Declaration").

Example 12 shows that transgenic tobacco plants over-expressing *GhMYB25* had increased trichome formation. The subject application also disclosed that over-expression of a *GhMYB25-like* transgene would also cause increased trichome formation on the leaves of transgenic tobacco plants. Further, the subject application also disclosed that increased trichome formation in tobacco indicates that the gene would cause increased fibre initiation and/or elongation if over-expressed in a transgenic fibre producing plant, e.g. using the methods described in Example 13.

Subsequent work confirmed that a *GhMYB25-like* transgene (encoding a polypeptide with an amino acid sequence identical to the amino acid sequence encoded by the nucleotide sequence set forth in SEQ ID NO: 38) increased fibre production when over-expressed in a fibre producing plant. The Danny Llewellyn Declaration, in paragraphs 11-20, describes experiments confirming that over-expression of *GhMYB25-like* in fibre producing plants results in an increase in the number of fibre initiations compared to wild-type plants. Furthermore, transgenic plants over-expressing *GhMYB25-like* were viable, and with the exception of increased fibre growth, appeared

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similar to wild-type plants. These experiments demonstrate that the disclosure within the subject application has been confirmed to be correct, and that the subject specification enables the invention as claimed.

Reduced Plant Fibre Initiation and/or Elongation Upon Reduced GhMYB25-like Expression

Example 5 and Table 4 of the subject specification show reduced expression of the *GhMYB25* and *GhMYB25-like* genes in a mutant fibre producing plant with reduced fibre initiation and/or elongation in the plant. Thus, the subject application discloses *GhMYB25* and *GhMYB25-like* to be "Fibre Initiation Genes", i.e. genes whose expression correlates with fibre initiation or elongation in fibre producing plants (Example 5). This discovery, which was disclosed for the first time in the subject specification enables a person of ordinary skill in the art to reduce fibre initiation and/or elongation in transgenic fibre producing plants by reducing expression of *GhMYB25-like* (see paragraphs 21-23 of the Danny Llewellyn Declaration). Additionally, Example 13 of the subject application provides methods for the creation of a fibre producing plant with reduced expression of *GhMYB25* or *GhMYB25-like*.

Subsequent work confirmed that there was reduced fibre production in a transgenic fibre producing plant upon the reduction of *GhMYB25-like* gene (SEQ ID NO: 38) expression. The Danny Llewellyn Declaration, in paragraphs 24-32, describes experiments confirming that reduced expression of *GhMYB25-like* in fibre producing plants results in reduced fibre initiation and/or elongation compared to wild-type

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plants. These experiments demonstrate that the disclosure within the subject application has been confirmed to be correct, and that the subject application enables the invention as claimed.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 117, 119-120, 123, 127, 129, 131, 133, 135-137 and 139 under 35 U.S.C. §112, first paragraph-enablement.

Rejection under 35 U.S.C. §101

On page 11 of the October 1, 2010 Office Action, the Examiner rejected claims 131 and 137 under 35 U.S.C. §101, as being directed to non-statutory subject matter. The Examiner alleged that the recitation "A host cell comprising" in claim 131 read on a human being. Additionally, the Examiner alleged that claim 137 read on the wild-type progeny produced by heterozygous transgenic parents.

Applicants' Reply

In response, without conceding the correctness of the Examiner's position but solely to expedite prosecution, applicants have hereinabove amended claim 131 to recite, "A plant or bacterial cell", which does not read on a human.

Applicants respectfully traverse the Examiner's rejection of Claim 137 which currently recites, "A transgenic seed of the plant of claim 133." A "transgenic seed" cannot also be a "wild-type seed", and is a seed containing a transgene. Thus, a "transgenic seed" cannot read on the wild-type progeny of heterozygous transgenic parents.

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Accordingly, the rejection of claims 131 and 137 under 35 U.S.C. §101 is moot.

Rejection under 35 U.S.C. §102

On page 12 of the October 1, 2010 Office Action, the Examiner rejected claims 127, 129, 131, 133, 137, and 139 under 35 U.S.C. §102(e), as allegedly being anticipated by Fincher. The Examiner stated that Fincher discloses a nucleic acid molecule of SEQ ID NO:3964 which exhibits 23% identity to applicants' SEQ ID NO:38 which the Examiner alleged would hybridize with applicants' SEQ ID NO:38.

Applicants' Reply

In response, applicants respectfully traverse. The hybridization of two sequences exhibiting only a 23% identity to each other is contrary to the expectation of one of ordinary skill in the art, especially under the stringent hybridization conditions taught in the subject application (paragraph [0301]). Regardless, the recitation "high stringency conditions" has been removed from the claims. Consequently, the Examiner cannot maintain a sequence of only 23% identity applicants' SEQ ID NO:38 anticipates the now pending claims.

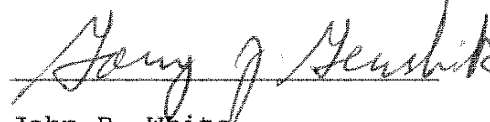
Accordingly, applicants respectfully request that all claims pending in the subject application be allowed.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invites the Examiner to telephone them at the number provided below.

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No fee, other than the \$130.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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ORIGINAL: English

DATE: March 11, 2004

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PATENT COOPERATION TREATY (PCT)

PCT INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION GUIDELINES

(Guidelines for the Processing by International Searching and
Preliminary Examining Authorities of International Applications
Under the Patent Cooperation Treaty)

as in force from March 25, 2004

1. This document contains the text, as in force from March 25, 2004, of the PCT International Search and Preliminary Examination Guidelines, established by the International Bureau of WIPO after consultation with the International Searching and Preliminary Examining Authorities under the PCT with a view, in particular, to implementing the amendments of the PCT Regulations which entered into force on January 1, 2004.
2. The Guidelines apply to the processing of international applications filed on or after January 1, 2004. They supersede the PCT International Search Guidelines, as in force from September 18, 1998 (document PCT/GL/IS/1), and the PCT International Preliminary Examination Guidelines, as in force from October 9, 1998 (document PCT/GL/IPE/1), which were published in Special Issues of the *PCT Gazette* Nos. S-06/1998 and S-07/1998, respectively. The text of the present Guidelines is the same (subject to minor editorial changes) as in the provisional version of this document (document PCT/GL/ISPE/1 Prov.2) which has been applicable, in practice, since January 1, 2004.
3. The text will also be published in Special Issue No. S-02/2004 (dated March 25, 2004) of the *PCT Gazette*.

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Exhibit 1

Chapter 10 Unity of Invention

Determination of Unity of Invention

Article 17(3)(a); Rule 13; Section 206

10.01 An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

Rule 13.2; AI Annex B, Part I(b)

10.02 Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.

Rule 13.2

10.03 Lack of unity of invention may be directly evident "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity *a priori* as there is no subject matter common to all claims. In the case of independent claims to A + X and A + Y, unity of invention is present *a priori* as A is common to both claims. However, if it can be established that A is known, there is lack of unity *a posteriori*, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

10.04 Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor persisted in on the basis of a narrow, literal or academic approach. There should be a broad, practical consideration of the degree of interdependence of the alternatives presented, in relation to the state of the art as revealed by the international search or, in accordance with Article 33(6), by any additional document considered to be relevant. If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others without there being any unifying novel inventive concept common to all, then clearly there is lack of unity of invention. If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then objection of lack of unity does not arise. For determining the action to be taken by the examiner between these two extremes, rigid rules cannot be given and each case is considered on its merits, the benefit of any doubt being given to the applicant.

10.05 From the preceding paragraphs it is clear that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority. However, the Authority should not raise objection of lack of unity of invention merely because the inventions claimed are classified in separate classification